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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,554

03/15/2006

Jeremy Marshall

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

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02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,554	Applicant(s) MARSHALL ET AL.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claim 5 is objected to because of the following informalities: Claim 5 includes "the housing" in line 3 which should read "the casing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following limitations lack antecedent basis:

5. Claim 1: limitation "the tip" in line 4.
6. Claim 2: limitation "the two webs" in line 2.
7. Claim 3: limitation "the exposed end in lines 2-3.
8. Claim 4: limitation "the free ends" in line 2.
9. Claim 12 includes the limitation "the forward free ends" in lines 15-16 and "said free ends" in line 18 and "the tip" in line 6.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 1, 3, and 4** are rejected under 35 U.S.C. 102(e) as being anticipated by Teo et al. (US 6,540,763; "Teo"). Teo discloses a lancet comprising a body having a drive head (40) at one end and a projecting needle (50) at the other end, the body having integral webs (44) projecting down both sides towards the location of the tip of the needle, the webs being of undulating form and of a flexible material so as to act as spring members (see configuration of webs 44 shown in fig. 12).

12. Regarding claims 3 and 4, the device further includes a removable protective cap (46; fig. 4) which is linked to the free ends of the webs by breakable connecting parts (48 can be considered linked to the ends of the web). Please see the 35 USC 112 2nd paragraph rejection above. Since "the free ends of the webs" lacks antecedent basis, it is being considered to mean free of direct connection with the drive head. The proximal ends opposite the free ends (44) are directly connected to the drive head. In this case, the distal ends of the drive head can be considered free ends.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claims 1-6, 10, and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (US 4,203,446; "Hofert") in view Kirk et al. (US 4,860,740; "Kirk"). Hofert discloses a

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lancet device comprising a casing and a lancet supported for reciprocatory movement in the casing between a cocked position and an advanced position, the lancet having a drive head (for example, 16) at one end and a projecting needle (12) at the other end, and a drive spring (36) positioned between the casing and the drive head of the lancet to drive the lancet and projecting needle into an advanced position in which the needle performs a pricking operation. Hofert also discloses a return spring (20) but does not disclose that this return spring is formed from two integral webs of undulating form and resilient material which project down both sides toward the needle tip.

15. However, Kirk teaches that it is well known to use two undulating web members (40) projecting down both sides of a medical device as a return spring to bias a portion of the device to its raised portion within a casing (fig. 1; col. 7 ll. 8-13). It would have been obvious to include such web members as a return spring instead of the coiled return spring (20) disclosed by Hofert because such a modification can be considered a simple substitution of one known spring mechanism for another where there is a reasonable expectation of success. One skilled in the art has good reason to pursue the known options within his or her technical grasp including various spring mechanisms. If this leads to the anticipated success, it is likely the product of ordinary skill and common sense. Regarding claim 12, the webs have free ends which abut surfaces of the casing so that they may be compressed, but Kirk does not expressly teach that the free ends are spaced from abutment surfaces of the casing at any time. However, this limitation does not patentably distinguish the claimed invention from the prior art of Hofert in view of Kirk as the free ends eventually engage the abutment surfaces, the spaces do not affect the way the web members perform as springs, and spacing the free ends slightly from the abutment surfaces when in the relaxed configuration would have been within the purview of one skilled in the art.

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16. Regarding claim 2, see fig. 1.

17. Regarding claim 6, Hofert discloses a movable rib (30) of the casing and a flexible button (40) on the casing which is movable to release the rib from the drive head to enable the drive spring to drive the lancet forwards. Hofert discloses the rib fitting into a recess (28) within the drive head. However, it would have been well within the purview of one skilled in the art to instead use a flange on the drive head upon which the rib rests instead of a recess on the drive head into which the rib fits since such a configuration would work in generally the same manner with the same result and it appears that a flange offers no advantage over the recess disclosed by Hofert.

18. Regarding claims 3, 4, and 10, although Hofert fails to disclose a removable protective cap, such a cap is very well known in the art as are breakable connecting parts between a cap and the remainder of a lancet device.

19. **Claims 7 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert in view of Kirk as applied to claims 5 and 6 above, and further in view of Tavel (US 3,375,381). Hofert in view of Kirk discloses the invention substantially as stated above and it would have been obvious to add a cap, also discussed above, in order to protect the user from accidental contact with the lancet needle as well as protecting the needle from contamination prior to use as is very well known in the art. Tavel teaches a connection between a cap and a casing of a device which includes a cap (12) that locates over flanges (raised surface above grooves 17 as viewed in fig. 1 which abuts bosses 16) on the casing, but can be twisted out of contact with the flanges to enable the cap to be removed to expose the casing. In particular, the cap may be twisted so that bosses (16) are twisted out of contact with (17) and aligned with channel (18) (col. 2, ll. 15-38) so that the cap may be removed. It would have been obvious to use the

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mechanism taught by Tavel to releasably connect a cap with the casing of Hofert as modified by Kirk in order to avoid accidental removal of the cap.

Response to Arguments

20. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 1/29/2009

/Anhtuan T. Nguyen/

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Supervisory Patent Examiner, Art Unit 3731